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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,387	01/12/2001	Michael Roger Cane	14409-9006-00	2484

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EXAMINER

SHAH, DEVAANG

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 03/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,387

Applicant(s)

CANE ET AL.

Examiner

Devaang, Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 18, 19, 24, 31-58, 60, and 61 is/are rejected.
- 7) ☒ Claim(s) 16, 17, 20-23, 25-30, 59, 62 and 63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 21 and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
2. Claim 21 recites the limitation "said calibration." There is insufficient antecedent basis for this limitation in the claim.
3. Claims 36-38 recite the limitation "said record." There is insufficient antecedent basis for this limitation in the claim.
4. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 34 is unclear in line 10, due to the phrase "along the or each line or at each point..." The claim is generally unclear in lines 4-8, as it is ambiguous whether a theoretical intensity of remitted light is to be derived only when using two wavelengths of which at least one is greater than 600 nm, or whether a theoretical intensity of remitted light is to be derived when using a single light having a wavelength sufficiently far into the infra-red range as well.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1-4,8,13-15,18, and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,081,612 to Gutkiewicz-Krusin et al.

6. Referring to claims 1-4 and 8, Gutkiewicz-Krusin et al. disclose systems and methods for non-invasive spectral imaging and characterization of skin tissue. The method includes illuminating an area of skin with light from three spectral bands and digitally imaging the area of skin with the remitted light. The digital images are comprised of digital signals whose values are functions of the skin condition. The images are processed and segmented by a processor. The processor outputs the condition of the skin by estimating values of skin parameters and comparing a weighted combination of these values to a threshold value. The threshold value may come from a training set of images that exemplify skin conditions (column 3, lines 53-67; column 4, lines 1-25).

7. Referring to claims 13-15,18, and 33, the spectral bands used in the method of Gutkiewicz-Krusin et al. comprise the center wavelength ranges of: 350-500 nanometers; 500-600 nm; and 750-1000 nm (column 4, lines 51-56). These ranges

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encompass UV, visible, and IR regions of the spectrum. Tissue color coordinates are measured, calibrated, and compared to reference parameters to assess the degree of abnormality. The calibration process uses an average of sequences of images of an illuminated, flat, diffuse reflectance standard such as a white target with greater than 99% reflectance to reduce the effect of spatial non-uniformities in the reflectance standard and to improve the signal to noise ratio. The data acquired is displayed either as normalized monochromatic images or color visualization images, both of which are dependent on intensity of light remitted (column 11, lines 26-67; column 12; column 13, lines 1-40; figures 3(a) and 3(b)).

8. Referring to claims 35, 39-49, and 52-57, the apparatus of Gutkowicz-Krusin et al. is shown in figures 1 and 2. The apparatus includes a light source (3), a photo-receptor (6), processing means to perform applications such as comparing variations (12), a filter wheel (29), polarization means both for illumination light and remitted light (31 and 31a), means to pass a control signal to a display device (12), means to carry out illumination in various spectral bands (4 and 27), means to monitor remitted light intensity (6 and 12), means for a flexible light guide (30a and 30b), and means to further carry out the methods of Gutkowicz-Krusin et al.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 24,31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gutkowicz-Krusin et al.

10. Referring to claim 24, Gutkowicz-Krusin et al. list spectral ranges and includes a center range of 750-1000 nm. If the spectral band has a center at about 1000 nm, the longer range of the band could include wavelengths at or greater than 1100 nm.

Furthermore, it would be obvious to one having ordinary skill in the art to extend the range of the center of said spectral band to 1100 nm in order to obtain data from deeper in the skin, as is well known in the art, because the method of Gutkowicz-Krusin et al. involves imaging the skin as well.

11. Referring to claims 31 and 32, Gutkowicz-Krusin et al. refer to a calibration sequence as described above in which a white standard is used to calibrate the images. Gutkowicz-Krusin et al. state that the purpose of said calibration is to eliminate such effects as variation in illumination pattern or aging in the lamp (column 11, lines 32-36).

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It would be obvious to one having ordinary skill in the art to calibrate an image for comparison with another image that was acquired under different conditions in order to achieve unbiased results. It is also obvious to one having ordinary skill in the art that such calibration is not necessary if the same lighting conditions and calibration set up are used to acquire all images.

12. Claims 5-7, 19, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gutkowicz-Krusin et al. in view of U.S. Patent No. 5,353,790 to Jacques et al.

13. Referring to claims 6, 7, and 58, the method of Gutkowicz-Krusin et al. includes comparing the remitted light from the area of interest to reference data. However the reference data does not come from a mathematical optical model of the tissue. Jacques et al. disclose a method and apparatus for the optical measurement of bilirubin in tissue. The method includes using an optical model of the skin to develop parameters for an algorithm to determine the amount of cutaneous bilirubin. The optical model accounts for melanin in the epidermis and for the dermis' collagen matrix (column 3, lines 5-36). It would be obvious to one having ordinary skill in the art to use the model of Jacques et al. with the method of Gutkowicz-Krusin et al. because Gutkowicz-Krusin et al. seek to distinguish abnormal skin from normal skin, and parameters derived from a mathematical model of normal skin would be useful to compare with acquired parameters from an area of interest in order to characterize the area of interest

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and minimize errors that could occur from miscalibration or random variations occurring during data acquisition.

14. Referring to claims 5 and 19, Gutkowicz-Krusin et al. do not include an independent measurement of the level of epidermal melanin. The method of Jacques et al. includes a measurement of the melanin level in order to eliminate the effects of melanin on the data for bilirubin (figure 37A). It would be obvious to one having ordinary skill in the art to use the measurement from the Jacques et al. method with the skin tissue characterization method of Gutkowicz-Krusin et al. in order to eliminate the effects of melanin so that the dermal structure could be analyzed.

15. Claims 9-12, 50, 51, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gutkowicz-Krusin et al. in view of Jacques et al. as applied to claims 6, 7, and 19 above, and further in view of U.S. Patent No. 5,784,162 to Cabib et al.

16. Referring to claims 9 and 10, the combined Gutkowicz-Krusin et al. and Jacques et al. reference does not include means for controlling a treatment process. Cabib et al. describe methods of spectral bio-imaging. Among possible applications described is photodynamic therapy (PDT). Cabib et al. state that a typical application includes skin imaging before, during, and after treatment to optimize the treatment time and minimize side effects. Using the modified Gutkowicz-Krusin et al. reference to control and predict PDT would be obvious to one having ordinary skill in the art because using spectral bio-imaging in conjunction with PDT was a known method at the time of the application.

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17. Referring to claims 11,12,50, 51,60, and 61, the modified Gutkowicz-Krusin et al. reference does not include endoscopic monitoring. Cabib et al. disclose an application of spectral bio-imaging for cancer tissue mapping for diagnosis and analysis before, during, and after an operation, and to visualize the borders of diseased tissue during an operation. The application includes using an endoscope for imaging internal body tissue with reflection of white light, auto-fluorescence, and laser induced fluorescence (column 25, lines 12-25). It would be obvious to one having ordinary skill in the art to use the endoscopic configuration of Cabib et al. with the method of Gutkowicz-Krusin et al. in order to analyze and monitor internal epithelial and sub-epithelial tissue. The apparatus of Gutkowicz-Krusin et al. would easily be modified to include an endoscopic probe because the light source already comprises a lamp and flexible optical fibers.

Allowable Subject Matter

18. Claims 16, 17, 20-23, 25-30,59,62, and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: U.S. Patent No. 5,986,770 to Hein et al.

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20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Devaang Shah whose telephone number is 703-306-0333. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on 703 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

DS *D.S.*
March 7, 2002



Marvin M. Lateef
Supervisory Patent Examiner
Group 3700